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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,891	01/02/2002	Jeffrey T. Borenstein	62030(51588)	8813
21874	7590	10/12/2005	EXAMINER	
EDWARDS & ANGELL, LLP			NAFF, DAVID M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1651

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,891

Applicant(s)

BORENSTEIN ET AL

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-38 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-26,28-32 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/3/05 has been entered.

The amendment of 7/01/05 after final rejection has been entered
10 as directed by the submission. The amendment amended claims 1, 5, 6, 14, 25 and 32, canceled claim 4 (3 previously canceled), and added new claim 38.

Claims 27 and 33-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention,
15 there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/21/04.

Claims examined on the merits are 1, 2, 5-26, 28-32 and 38.

The text of those sections of Title 35, U.S. Code not included in
20 this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.
112:

25 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1651

Claims 1, 2, 5-26, 28-32 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear how "micromachined" defines the polymer scaffold since being micromachined results from a process step of micromachining in a process of making the scaffold. The claims fail to specify how micromachining is performed in a process of making the scaffold. Without knowing how micromachining is used to make the scaffold, the way in which "micromachined" defines the scaffold cannot be determined. It would be uncertain as to the difference in a micromachined scaffold and a scaffold that is not micromachined.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-26, 28-32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (6,143,293) in view of Vacanti et al (6,139,574) and Mastrangelo et al (6,136,212), and if necessary in further view of Cima et al (5,518,680) or Marra et al (6,165,486).

The claims are drawn to a multilayer device containing a first layer of a micromachined polymer scaffold for attachment and culturing of cells and containing a pattern of microchannels, and a second layer of a micromachined polymer scaffold for attachment and culturing of cells, and the first and second layers being fastened together.

Art Unit: 1651

Weiss et al disclose a scaffold containing multiple layers fastened together for cell culture that is the same as presently claimed except for the presence of microchannels.

Vacanti et al disclose a scaffold for tissue regeneration
5 containing interconnected pores.

Mastrangelo et al disclose producing microfluidic devices containing micromachined microchannels.

It would have been obvious to provide layers of the scaffold of Weiss et al with interconnecting micromachined microchannels as
10 suggested by Vacanti et al disclosing a scaffold having interconnected pores and Mastrangelo et al disclosing producing microfluidic devices having micromachined microchannels. Micromachined microchannels in the scaffold of Weiss et al would have been expected to be advantageous for the same type of reason that Mastrangelo et al found
15 such channels to be advantageous. Providing microchannels about 10 to 50 microns in diameter as in claim 38 would have been a matter of obvious choice depending on the size of cells desired to enter the channels, and would have been a matter of individual preference well within the skill of the art. If needed, Cima et al or Marra et al
20 would have further suggested scaffold structure. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The methods of claims 25, 26 and 28-32 would have been obvious methods of making the scaffold in view of the methods disclosed by the references.

Response to Arguments

Applicant's arguments filed 7/1/05 have been fully considered but they are not persuasive.

Applicants have pointed out what each reference discloses, and
5 how the reference differs from the invention. However, the references are applied in combination, and the invention becomes obvious when the references are considered together as a whole rather than each alone. Microfabrication is clearly suggested by Mastrangelo et al by disclosing devices having micromachined channels. It would have been
10 clearly obvious to provide the scaffold of Weiss with micromachined channels for their function as taught by Mastrangelo et al. Applicants refer to paragraph 196 of the specification as demonstrating a resolution of 2 μ m. However, the present claims do not require a microfabricated scaffold produced as in paragraph 196 of
15 the specification. As to microchannels of about 10 to 50 microns in diameter as required by claim 38, the scaffold of Weiss et al can contain pores of 200-400 microns (col 2, line 60) and the matrix of Vacanti et al can have pores of 5-80 microns (col 15, line 39) or 10-20 microns (col 12, line 61) and channels of 60-300 microns (col 17,
20 line 18). Thus, it would have been apparent to the ordinary skilled artisan that pore size can vary, and will depend on preferred size desired for a particular use or cell size to enter the scaffold. The specification discloses that channel size can be 5-500 microns (paragraph 78), and no critically has been established in using a
25 channel size of 10-50 microns. The specification discloses that this

Art Unit: 1651

channel size is merely a size for endothelial cells to enter. Weiss
et al disclose that current approaches use a type of scaffold material
to promote one type cell growth. When the cell type is endothelial
cells, it would have been obvious to select a channel size for these
5 cells instead of for bone cells as in Weiss et al. Selecting a
particular channel size merely because the size allows a certain cell
to enter would have been obvious and within the ordinary skill of the
art.

Conclusion

10 Any inquiry concerning this communication or earlier
communications from the examiner should be directed to David M. Naff
whose telephone number is 571-272-0920. The examiner can normally be
reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
15 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-
0926. The fax phone number for the organization where this
application or proceeding is assigned is 751-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

10/11/05